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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,540	03/23/2004	Jorge L. Orbay	HAN-031	2499

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EXAMINER	
SHAFFER, RICHARD R	
ART UNIT	**PAPER NUMBER**
3733	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,540	ORBAY ET AL.	
	Examiner	Art Unit	
	Richard R. Shaffer	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-19,21-24 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-19,21-24 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Withdrawal of Previous Finality

The previous has been withdrawn effective as of the mailing of the Pre-Appeal Brief Conference decision mailed on December 28th, 2006. The following is a Non-Final Rejection under new grounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 19, 20, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant alleges that the newly added limitation in the independent **claim 1** of "an outer surface that defines an outer diameter is **at least approximately five** times a radial wall thickness of said cap at said engagement portion" and in independent **claim 19** of "a wall with a radial wall thickness, an outer diameter **at least approximately five** times said radial wall thickness" are supported by the specification between **Page 5, Line 6 and Page 6, Line 8**. However, the specification merely defines the ranges preferred for the outer and inner diameters of the device. With even calculating with an outer diameter of 0.110 inch (outer diameter of E) and 0.067 inch (inner diameter of F)

which would create the thickest wall results in a radial wall thickness of 0.0215 inch. This value means the **minimum possible ratio** of an outer diameter to radial wall thickness is **~5.11**. Approximately five times includes values at five and below five, which are not disclosed in the specification. Further, the limitation of stating "**at least**" in **claims 1, 19, and 27** leave the range open ended. Again, clearly applicant does not have support for a ratio including infinity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 13-19, 21-24 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simmons et al (US Patent 5,894,110) in view of Schultz (US Patent 4,688,56) and further evidenced by PINCAP® Orthopedic Pin Protectors (2001).

Simmons et al disclose a resilient plastic (**Column 2, Lines 63-67**) cap comprising: a cylindrical lead-in portion with a first inner diameter (at **16, Figure 2**); a cylindrical engagement tubular portion (rest of the device) which is longer than the lead-in portion; the engagement portion defines a second inner diameter (where **18** is pointing, **Figure 2**) smaller than the first inner diameter; the outer diameter of the engagement portion at **18** is clearly at least 5 times the radial wall thickness at that point; an annular ring (hump at **26**) with a convex outer surface defines a third inner diameter; a fourth inner diameter larger than the third inner diameter and less than the

second diameter is located just above the hump (**26, Figure 2**); the end (**24**) of the cap (**10**) is closed.

Simmons et al disclose all of the claimed limitations except for the device being made specifically of radiopaque polyurethane, the lead-in portion having an inner diameter of 0.080-0.092 inch, the engagement portion having an inner diameter of 0.070-0.084 inch, having a length 0.285-0.310 inch, and for the use of a orthopedic pin.

Simmons et al did disclose in **Column 2, Lines 63-67** that the device is made of "a polymeric material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Schultz teaches (**Column 1, Line 55 through Column 2, Line 17**) that his device can take the form of a wire coil such as frequently used for joining electrical wire to cover the ends of Kirshner wire (or Steinman pin or similar product as described in **Column 1, Lines 15-20**) whether it protrudes through the skin or is entirely internal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of Simmons et al in the field of orthopedics to protect the ends of Kirshner wire or Steinman pins in order to market a product to a greater customer base due to demonstrated success by Schultz. It would have been further obvious to make the device of Simmons et al radiopaque when fully enclosed in the body. The device of Schultz was made of metal and would inherently be radiopaque. It

is well known in the art that objects placed in the body preferably are detected at least partially by x-ray to view their position (when delivering implants or fluids or when merely checking the status of a permanent or temporary implant) as supported by PINCAP® which uses radiopaque caps for orthopedic pins. It is further well known in the art that a polymer can be infused with barium sulfate (as well as other compounds) to achieve radiopacity.

As for the dimensional requirements, it is noted that such requirements are dependent upon which the cap will be placed. In the instant case, this is a Kirshner wire or pin, which is the same as applicant's intended use. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the set of dimensions since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 1-11, 13-19, 21-24 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markiewitz et al (US Patent Application Publication 2003/0215307) in view of Schultz and further evidenced by PINCAP® Orthopedic Pin Protectors (2001).

Markiewitz discloses a resilient plastic (**Column 3, Paragraph 0040**) cap (i.e. **Figure 7**) for covering orthopedic wires and pins (**11**) comprising: a cylindrical lead-in portion (Right Portion in **Figure 7** extending slightly left) with a first inner diameter (Initial Open Diameter); a cylindrical engagement tubular portion (remainder of device) which is longer than the lead-in portion; the engagement portion defines a second inner diameter

(where the **right arm 24** is pointing, **Figure 7**) smaller than the first inner diameter; the outer diameter of the engagement portion is clearly at least 5 times the radial wall thickness; an annular ring (**middle 23**) with a convex outer surface that defines a third inner diameter; a fourth inner diameter larger than the third inner diameter and less than the second diameter (where the **left arm of 24** is pointing, **Figure 7**); the end (**25**) of the cap (**10**) is closed.

Markiewitz et al disclose all of the claimed limitations except for the device being made specifically of radiopaque polyurethane, the lead-in portion having an inner diameter of 0.080-0.092 inch, the engagement portion having an inner diameter of 0.070-0.084 inch and the cap having an overall length of 0.285-0.310 inch.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

It would have been further obvious to one having ordinary skill in the art at the time the invention was made to determine the claimed dimensional requirements, since it is noted that such requirements are dependent upon which the cap will be placed. In the instant case, this is an orthopedic wire or pin, which is the same as applicant's intended use. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the set of dimensions since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Schultz teaches (**Column 1, Line 55 through Column 2, Line 17**) orthopedic pins and wires are sometimes entirely enclosed by the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make it radiopaque when used within the body. The device of Schultz was made of metal and would inherently be radiopaque. It is well known in the art that objects placed in the body preferably are detected at least partially by x-ray to view their position (when delivering implants or fluids or when merely checking the status of a permanent or temporary implant) as supported by PINCAP® which uses radiopaque caps for orthopedic pins. It is further well known in the art that a polymer can be infused with barium sulfate (as well as other compounds) to achieve radiopacity.

Response to Arguments

Applicant's arguments with respect to the prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed November 20th, 2006 in respect to the new matter rejections have been fully considered but they are not persuasive. It has been further described how the range limitations are not supported by the specification as originally filed in this current Office Action. Applicant is again instructed to cancel the limitations, or in their stead, insert the ranges as claimed in claims 16-18 in the independent claims if such dimensional values are deemed to be the novelty of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Richard Shaffer

Richard Shaffer
March 4th, 2007

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER